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105TH CONGRESS
2D SESSION

H. R. 4753

To amend title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs and home infusion drug therapy under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 8, 1998

Mr. STARK introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to provide for coverage of outpatient prescription drugs and home infusion drug therapy under the Medicare Program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Medicare Prescription Drug Coverage Act of 1998".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Coverage of outpatient prescription drugs.
Sec. 3. Payment rules and related requirements for covered outpatient drugs.
Sec. 4. Medicare rebates for covered outpatient drugs.
Sec. 5. Expansion of Medicare payment advisory commission.
Sec. 6. Coverage of home infusion drug therapy services.
Sec. 7. No mark-up for drugs, biologicals, or parenteral nutrients.
Sec. 8. Treatment of part B premium increases resulting from enactment.
Sec. 9. Effective date.

SEC. 2. COVERAGE OF OUTPATIENT PRESCRIPTION DRUGS.

(a) COVERED OUTPATIENT DRUGS AS MEDICAL AND OTHER HEALTH SERVICES.—Section 1861(s)(2)(J) of the Social Security Act (42 U.S.C. 1395x(s)(2)(J)) is amended to read as follows:

"(J) covered outpatient drugs;".

(b) DEFINITION OF COVERED OUTPATIENT DRUG.—Section 1861(t) of such Act (42 U.S.C. 1395x(t)) is amended—

(1) in the heading, by adding at the end the following: "; Covered Outpatient Drugs";

(2) in paragraph (1)—

(A) by striking "paragraph (2)" and inserting "the succeeding paragraphs of this subsection", and

(B) by striking the period at the end and inserting ", but only if used for a medically accepted indication (as described in paragraph (4))."; and

(3) by striking paragraph (2) and inserting the following:

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"(2) Except as otherwise provided in paragraph (3), the term 'covered outpatient drug' means any of the following products used for a medically accepted indication (as described in paragraph (4)):

"(A) A drug which may be dispensed only upon prescription and—

"(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

"(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a 'new drug' (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

"(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

"(B) A biological product which—

"(i) may only be dispensed upon prescription,

"(ii) is licensed under section 351 of the Public Health Service Act, and

"(iii) is produced at an establishment licensed under such section to produce such product.

"(C) Insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

"(D) Enteral nutrients (but only if provided as a covered home infusion drug).

"(E) Medically-necessary foods for persons with Phenylketonuria (PKU) and other inborn errors of metabolism, in accordance with guidelines developed by the Secretary.

"(3) The term 'covered outpatient drug' does not include any product—

"(A) which is administered through infusion in a setting described in paragraph (5)(A)(ii) unless the product is a covered home infusion drug (as defined in paragraph (5));

"(B) when furnished as part of, or as incident to, a diagnostic service or any other item or service for which payment may be made under this title (other than physicians' services or services which would be physicians' services if furnished by a physician); or

"(C) which is listed under paragraph (2) of section 1927(d) (other than subparagraph (B), (I), or (J) of such subparagraph) as a drug which may be excluded from coverage under a State plan under

title XIX and which the Secretary elects to exclude from coverage under part B.

"(4) For purposes of paragraph (2), the term 'medically accepted indication', with respect to the use of an outpatient drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—

"(A) the drug has been approved by the Food and Drug Administration; and

"(B)(i) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information, and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

"(ii) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appear-

ing in publications which have been identified for purposes of this clause by the Secretary.

The Secretary may revise the list of compendia in subparagraph (B)(i) designated as appropriate for identifying medically accepted indications for drugs.

"(5)(A) For purposes of paragraph (3), the term 'covered home infusion drug' means a covered outpatient drug dispensed to an individual that—

"(i) is administered intravenously, subcutaneously, or epidurally, using an access device that is inserted into the body and an infusion device to control the rate of flow of the drug (or through other means of administration determined by the Secretary);

"(ii) is administered—

"(I) in the individual's home,

"(II) an institution used as the individual's home, but only if the drug is administered during an inpatient day for which payment is not made to the institution under part A for inpatient or extended care services furnished to the individual, or

"(III) in a facility other than the individual's home if the administration of the drug at the facility is determined by the Secretary to be

cost-effective (in accordance with such criteria as the Secretary may establish); and

"(iii) with respect to a drug furnished in a home setting—

"(I) is an antibiotic drug and the Secretary has not determined, for the specific drug or the indication to which the drug is applied, that the drug cannot generally be administered safely, effectively, and cost effectively in such a setting, or

"(II) is not an antibiotic drug and the Secretary has determined, for the specific drug or the indication to which the drug is applied, that the drug can generally be administered safely, effectively, and cost effectively in such a setting.

"(B) Not later than January 1, 2002 (and periodically thereafter), the Secretary shall publish a list of the drugs, and indications for such drugs, that are covered home infusion drugs, with respect to which home infusion drug therapy may be provided under this title.

"(C) In this paragraph, the term 'cost effectively' means, with respect to a home infusion drug, a determination by the Secretary that the coverage of the drug in a non-hospital setting will, considering all expenses, result

in lower expenditures under this title than if the drug were not so covered.".

(c) CONFORMING AMENDMENTS REPEALING SEPARATE COVERAGE OF CERTAIN DRUGS AND PRODUCTS.—(1) Effective January 1, 2002, section 1861(s)(2) of such Act (42 U.S.C. 1395x(s)(2)) is amended—

(A) in subparagraph (A), by striking "(including drugs" and all that follows through "self-administered)";

(B) by striking subparagraphs (G), (I), (O), (Q), and (T);

(C) by adding "and" at the end of subparagraph (R); and

(D) by striking "; and" at the end of subparagraph (S) and inserting a period.

(2) Effective January 1, 2002, section 1861 of such Act (42 U.S.C. 1395x) is amended by striking the subsection (kk).

(3) Effective January 1, 2002, section 1881(b) of such Act (42 U.S.C. 1395rr(b)) is amended—

(A) in the first sentence of paragraph (1)—

(i) by striking ", (B)" and inserting ", and (B)", and

(ii) by striking ", and (C)" and all that follows and inserting a period;

(B) in paragraph (11)—

(i) by striking "(11)(A)" and inserting "(11)", and

(ii) by striking subparagraphs (B) and (C).

SEC. 3. PAYMENT RULES AND RELATED REQUIREMENTS FOR COVERED OUTPATIENT DRUGS.

(a) IN GENERAL.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by inserting after subsection (d) the following new subsection:

"(e) PAYMENT FOR AND CERTAIN REQUIREMENTS CONCERNING COVERED OUTPATIENT DRUGS.—

"(1) DEDUCTIBLE.—

"(A) IN GENERAL.—Payment shall be made under paragraph (2) only for expenses incurred by an individual for a covered outpatient drug during a calendar year after the individual has incurred expenses in the year for such drugs (during a period in which the individual is entitled to benefits under this part) equal to the deductible amount for that year.

"(B) DEDUCTIBLE AMOUNT.—

"(i) For purposes of subparagraph (A), subject to clause (iii), the deductible amount is—

"(I) for 2002, an amount equal to $____; and

"(II) for any succeeding year, the amount applicable under this subparagraph for the previous year, increased by the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year (or, if lower, the percentage increase in the pharmaceutical component of such index for such period).

"(ii) The Secretary shall promulgate the deductible amount for 2003 and each succeeding year not later than October 1 of the previous year.

"(iii) If the deductible amount computed under clause (i)(II) for a year is not a multiple of $10, the Secretary shall (for that year only) round it to the nearest multiple of $10.

"(2) PAYMENT AMOUNT.—

"(A) IN GENERAL.—Subject to the deductible established under paragraph (1), the

amount payable under this part for a covered outpatient drug furnished to an individual during a calendar year shall be equal to—

"(i) 80 percent of the payment basis described in paragraph (3), in the case of an individual who has not incurred expenses for covered outpatient drugs during the year (including the deductible imposed under paragraph (1)) in excess of the out-of-pocket limit for the year under subparagraph (B); and

"(ii) 100 percent of the payment basis described in paragraph (3), in the case of any other individual.

"(B) OUT-OF-POCKET LIMIT DESCRIBED.—

"(i) For purposes of subparagraph (A), the out-of-pocket limit for a year is equal to—

"(I) for 2002, $____; and

"(II) for any succeeding year, the amount applicable under this subparagraph for the previous year, increased by the percentage increase described in paragraph (1)(B)(i)(II).

"(ii) The Secretary shall promulgate the out-of-pocket limit for 2003 and each succeeding year not later than October 1 of the previous year.

"(iii) If the out-of-pocket limit computed under clause (i)(II) for a year is not a multiple of $10, the Secretary shall (for that year only) round it to the nearest multiple of $10.

"(3) PAYMENT BASIS.—For purposes of paragraph (2), the payment basis is the lesser of—

"(A) the actual net payment for a covered outpatient drug, or

"(B) the applicable payment limit established under paragraph (4).

"(4) PAYMENT LIMITS.—

"(A) PAYMENT LIMIT FOR SINGLE SOURCE DRUGS AND MULTIPLE SOURCE DRUGS WITH RESTRICTIVE PRESCRIPTIONS.—In the case of a covered outpatient drug that is a multiple source drug which has a restrictive prescription, or that is single source drug, the payment limit for a payment calculation period is equal to the amount of the administrative allowance (established under paragraph (5)) plus the product of

the number of dosage units dispensed and the per unit actual acquisition cost for the drug product (determined under subparagraph (C)) for the period.

"(B) PAYMENT LIMIT FOR MULTIPLE SOURCE DRUGS WITHOUT RESTRICTIVE PRESCRIPTIONS.—In the case of a drug that is a multiple source drug which does not have a restrictive prescription, the payment limit for a payment calculation period is equal to the amount of the administrative allowance (established under paragraph (5)) plus the product of the number of dosage units dispensed and the lowest actual acquisition cost (determined under subparagraph (C)) of any of the multiple source drugs in the category as determined by the Secretary for the period.

"(C) DETERMINATION OF UNIT PRICE.—

"(i) INITIAL PAYMENT CALCULATION PERIOD.—The Secretary shall determine, for the dispensing of a covered outpatient drug product in the payment calculation period beginning January 1, 2002, the actual acquisition cost for the drug product, based upon—

"(I) in the case of a single source drug or multiple source drug with a restrictive prescription, based upon information from the period beginning in 1998 updated (in a compound manner) by the percentage change in the consumer price index for all urban consumers (U.S. city average) for the 4 12-month periods ending with June 2001; or

"(II) in the case of a multiple source drug without a restrictive prescription, based upon information from the most recent year for which data is available.

"(ii) SUBSEQUENT PERIODS.—The actual acquisition cost for a covered outpatient drug product applicable under this subparagraph for the dispensing of a drug product in a payment calculation period beginning in January of each year (beginning with 2003) shall be equal to the actual acquisition cost for the product determined under this subparagraph for the period ending in January of the previous

year, increased by the percentage increase described in paragraph (1)(B)(i)(II).

"(iii) SIMPLIFICATION IN DETERMINATION OF ACTUAL ACQUISITION COST.—The Secretary shall consult with the provider community to simplify the accounting and reporting requirements used in calculating actual acquisition cost and may accept various averaging procedures, tax documents, and tax accounting procedures (such as last-in-first-out (LIFO) and first-in-first-out (FIFO)) instead of new reporting requirements.

"(iv) COMPLIANCE WITH REQUEST FOR INFORMATION.—If a wholesaler or direct seller of a covered outpatient drug refuses, after being requested by the Secretary, to provide price information requested to carry out clauses (i) or (ii), or deliberately provides information that is false, the Secretary may impose a civil money penalty of not to exceed $10,000 for each such refusal or provision of false information. The provisions of section 1128A (other than subsections (a) and (b))

shall apply to civil money penalties under the previous sentence in the same manner as they apply to a penalty or proceeding under section 1128A(a). Information gathered pursuant to clause (i) or (ii) shall not be disclosed except as the Secretary determines to be necessary to carry out the purposes of this part and to permit the Comptroller General and the Director of the Congressional Budget Office to review the information provided.

"(D) DEMONSTRATION OF ALTERNATIVE PURCHASING ARRANGEMENTS.—The Secretary may conduct demonstrations with different forms of purchasing, such as competitive bidding, preferred provider organizations, bundling of medical and pharmaceutical costs, and other devices to obtain the lowest possible price for quality pharmaceutical products under this part. If the Secretary determines that a demonstration results in lower costs to the program and beneficiaries under this title while maintaining the quality and access to needed products, the Secretary may implement the demonstration regionally or nationally. The Sec-

retary shall from time to time report to Congress on demonstrations conducted under this subparagraph.

"(5) ADMINISTRATIVE ALLOWANCE FOR PURPOSES OF PAYMENT LIMIT.—

"(A) IN GENERAL.—Except as provided in subparagraphs (B) through (D), the administrative allowance established under this paragraph is—

"(i) for 2002, an amount equal to $____; and

"(ii) for each succeeding year, the amount for the previous year, adjusted by the percentage increase described in paragraph (1)(B)(i)(II).

"(B) SPECIAL RULE.—The Secretary shall establish a higher administrative allowance under subparagraph (A) in the case of compounding, consultation, and to ensure access to covered drugs and antigens that entail extra or unusual expense.

"(C) REDUCTION FOR MAIL ORDER PHARMACIES.—The Secretary may, after consulting with representatives of pharmacists, individuals enrolled under this part, and of private insur-

ers, reduce the administrative allowances established under subparagraph (A) for any covered outpatient drug dispensed by a mail order pharmacy, based on differences between such pharmacies and other pharmacies with respect to operating costs and other economies.

"(D) NO DISPENSING FEE FOR CERTAIN DRUGS AND PRODUCTS.—No administrative allowance may be provided under this paragraph with respect to any of the following covered outpatient drugs, unless the Secretary determines that an administrative allowance is necessary to assure access:

"(i) Erythropoietin provided to dialysis patients.

"(ii) Drugs and biologicals provided as an incident to a physician's service or to a service which would be a physician's service if furnished by a physician.

"(iii) Covered home infusion drugs.

"(6) ASSURING APPROPRIATE PRESCRIBING AND DISPENSING PRACTICES.—

"(A) IN GENERAL.—The Secretary shall develop a program to—

"(i) provide on-line prospective review of prescriptions on a 24-hour basis (in accordance with subparagraph (B)) and retrospective review of claims;

"(ii) establish standards for counseling individuals to whom covered outpatient drugs are prescribed; and

"(iii) identify (and to educate physicians, patients, and pharmacists concerning)—

"(I) instances or patterns of unnecessary or inappropriate prescribing or dispensing practices for covered outpatient drugs,

"(II) instances or patterns of substandard care with respect to such drugs,

"(III) potential adverse reactions, and

"(IV) appropriate use of generic products.

"(B) PROSPECTIVE REVIEW.—

"(i) IN GENERAL.—The program under this paragraph shall provide for on-line prospective review of each covered out-

patient drug prescribed for a patient before the prescription is filled or the drug is furnished, including screening for potential drug therapy problems due to therapeutic duplication, drug-to-drug interactions, and incorrect drug dosage or duration of drug treatment, including inadequate pain management therapy.

"(ii) DISCUSSION OF APPROPRIATE USE.—In conducting prospective review under this subparagraph, any individual or entity that dispenses a covered outpatient drug shall offer to discuss with the patient to whom the drug is furnished or the patient's caregiver (in person if practicable, or through access to a toll-free telephone service) information regarding the appropriate use of the drug, potential interactions between the drug and other drugs dispensed to the individual, the need for adequate pain management, and such other matters as the Secretary may require.

"(iii) ADDITIONAL DUTIES.—In carrying out this subparagraph, the Secretary shall—

"(I) develop public domain software which could be used by carriers and pharmacies to provide the on-line prospective review; and

"(II) study the feasibility and desirability of requiring confidential, encoded patient diagnosis codes on prescriptions and the feasibility of expanding the prospective review program to include the identification of drug-disease contraindications, interactions with over-the-counter drugs, and drug-allergy interactions.

"(C) PRIOR AUTHORIZATION.—

"(i) DEVELOPMENT OF LIST OF MISUSED DRUGS.—The Secretary shall develop (and periodically) update a list of covered outpatient drugs which the Secretary has determined, based on data collected, may be subject to misuse or inappropriate use. The Secretary shall provide a means for

manufacturers to appeal an initial decision to include a drug on the list.

"(ii) PRIOR AUTHORIZATION FOR DRUGS ON LIST.—The Secretary shall establish a process under which (subject to clause (iii)) the Secretary may require advance approval for any covered outpatient drug included on the list developed under clause (i), and the Secretary shall develop exceptions for oncologists, medical directors of hospice programs, and others who are or should be regularly involved in aggressive pain management.

"(iii) RESTRICTIONS ON DENIAL OF APPROVAL.—The Secretary may not deny the approval of a drug under the process established under clause (ii) before its dispensing unless the process—

"(I) provides responses by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

"(II) provides for the dispensing of at least a 72-hour supply of a cov-

ered outpatient prescription drug in emergency situations.

"(D) DRUG USE REVIEW.—As part of the program established under subparagraph (A), the Secretary shall provide for a drug use review program to provide for the ongoing periodic examination of claims data and other records on covered outpatient drugs furnished to patients under this title in order to identify patterns of fraud, abuse, gross overuse or underuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients.

"(E) EXCEPTION FOR MANAGED CARE PROGRAMS.—The Secretary may waive the application of any provision of this paragraph to the dispensing of covered outpatient drugs by an organization described in section 1833(a)(1)(A) or a Medicare+Choice organization under part C to the extent the Secretary finds that the organization has in effect a program that meets the objectives of such provision.

"(F) ADOPTION OF MEDICAID PROGRAMS.—To the extent considered appropriate

by the Secretary, the program developed under this paragraph with respect to drugs furnished in a State may include elements applicable to the furnishing of covered outpatient drugs under the State Medicaid program under section 1927.

"(7) ADMINISTRATIVE AND REPORTING REQUIREMENTS.—

"(A) REQUIREMENTS RELATING TO CONTROLLED SUBSTANCES AND ILLEGAL USES.—The Secretary shall require an entity furnishing covered outpatient drugs under this part to report electronically to the appropriate State agency on any covered outpatient drugs dispensed to individuals enrolled under this part that are controlled substances under schedules II through V of the Controlled Substance Act, and on the illegal use or diversion of any such drugs furnished by the entity.

"(B) PRIVACY PROTECTION.—The Secretary shall establish standards to protect from public disclosure the identity of any individual (whether a patient or an individual involved in the prescribing, dispensing, or administration of

the drug) who is the subject of information under this section. Under such standards—

"(i) no information on the use of a pharmaceutical by an identifiable individual shall be shared with anyone other than the individual, the individual's legal guardian or custodian, or the individual's physician;

"(ii) no information shall be shared with the individual's employer, or with a pharmaceutical manufacturer or wholesaler, or with any other individual for purposes of contacting the individual to persuade, sell, or influence the individual's choice of pharmaceuticals; and

"(iii) no physician, pharmacist, or other health care provider who receives any form of compensation or thing of value from a drug manufacturer or wholesaler may contact a patient for purposes of influencing the patient to use the product of that drug manufacturer or wholesaler.

"(C) STANDARD CLAIMS FORM.—The Secretary shall develop, in consultation with representatives of pharmacies and of other inter-

ested persons, a standard claims form for covered outpatient drugs in accordance with part C of title IX.

"(8) BILLING REQUIREMENTS.—

"(A) MANDATORY ASSIGNMENT.—(i) Payment under this part for a covered outpatient drug may only be made on an assignment-related basis.

"(ii) Except for deductible, coinsurance, or copayment amounts applicable under this part, no person may bill or collect any amount from an individual enrolled under this part or other person for a covered outpatient drug for which payment may be made under this part, and no such individual or person is liable for payment of any amounts billed in violation of this clause. If a person knowingly and willfully bills or collects an amount in violation of the previous sentence, the Secretary may apply sanctions against such person in accordance with section 1842(j)(2). Paragraph (4) of section 1842(j) shall apply in this clause in the same manner as such paragraph applies to such section.

"(B) USE OF ELECTRONIC SYSTEM.—The Secretary shall establish, by not later than July

1, 2001, a point-of-sale electronic system for use by carriers and pharmacies in the submission of information respecting covered outpatient drugs dispensed to Medicare beneficiaries under this part. Such system shall be consistent with the standards established by the National Council of Prescription Drug Programs, and to the maximum extent possible shall be based on current industry best practices.

"(9) DEFINITIONS.—In this subsection:

"(A) MULTIPLE AND SINGLE SOURCE DRUGS.—The terms 'multiple source drug' and 'single source drug' have the meanings of those terms under section 1927(k)(7), except that the reference in such section to a 'covered outpatient drug' shall be considered a reference to a covered outpatient drug under this title.

"(B) RESTRICTIVE PRESCRIPTION.—A drug has a 'restrictive prescription' only if—

"(i) in the case of a written prescription, the prescription for the drug indicates, in the handwriting of the physician or other person prescribing the drug and with an appropriate phrase (such as 'brand

medically necessary') recognized by the Secretary, that a particular drug product must be dispensed, or

"(ii) in the case of a prescription issued by telephone—

"(I) the physician or other person prescribing the drug (through use of such an appropriate phrase) states that a particular drug product must be dispensed, and

"(II) the physician or other person submits to the pharmacy involved, within 30 days after the date of the telephone prescription, a written confirmation which is in the handwriting of the physician or other person prescribing the drug and which indicates with such appropriate phrase that the particular drug product was required to have been dispensed.

The requirement of subclause (II) may be satisfied in such alternative manner, included electronic transmission of appropriate information, as the Secretary, after consultation with physicians and providers,

finds will reduce paperwork and administrative costs while maintaining program integrity.

"(C) PAYMENT CALCULATION PERIOD.—The term 'payment calculation period' means a calendar year.".

(b) REQUIRING PHARMACIES TO SUBMIT CLAIMS.—Section 1848(g)(4) of such Act (42 U.S.C. 1395w–4(g)(4)) is amended—

(1) in the heading—

(A) by striking "PHYSICIAN SUBMISSION" and inserting "SUBMISSION", and

(B) by inserting "BY PHYSICIANS AND SUPPLIERS" after "CLAIMS";

(2) in the matter in subparagraph (A) preceding clause (i)—

(A) by striking "For services furnished on or after September 1, 1990, within 1 year" and inserting "Within 1 year (or 90 days in the case of covered outpatient drugs)",

(B) by striking "a service" and inserting "an item or service", and

(C) by inserting "or of providing a covered outpatient drug," after "basis,"; and

(3) in subparagraph (A)(i), by inserting "item or" before "service".

(c) SPECIAL RULES FOR CARRIERS.—

(1) USE OF CARRIERS.—Section 1842(b)(2) of such Act (42 U.S.C. 1395u(b)(2)) is amended by adding at the end the following:

"(F) With respect to activities related to covered outpatient drugs, the Secretary may enter into contracts with carriers under this section to perform the activities on a regional or national basis.".

(2) ADDITIONAL FUNCTIONS.—Section 1842(b)(3) of such Act (42 U.S.C. 1395u(b)(3)) is amended—

(A) by striking "and" at the end of subparagraph (H); and

(B) by inserting after subparagraph (H) the following new subparagraphs:

"(I) if it makes determinations or payments with respect to covered outpatient drugs, will—

"(i) receive information transmitted under the electronic system established under section 1834(e)(8)(B), and

"(ii) respond to requests by pharmacies (and individuals entitled to benefits under this part) as to whether or not such an individual

has met the prescription drug deductible established under section 1834(e)(1)(B) for a year;

"(J) will enter into such contracts with organizations described in subsection (f)(3) as the Secretary determines may be necessary to implement and operate (and for related functions with respect to) the electronic system established under section 1834(e)(8)(B) for covered outpatient drugs under this part; and".

(3) PAYMENT ON OTHER THAN A COST BASIS.—Section 1842(c)(1) of such Act (42 U.S.C. 1395u(c)(1)) is amended—

(A) by inserting "(A)" after "(c)(1)",

(B) in the first sentence, by inserting ", except as otherwise provided in subparagraph (B)," after "under this part, and", and

(C) by adding at the end the following:

"(B) To the extent that a contract under this section provides for activities related to covered outpatient drugs, the Secretary may provide for payment for those activities based on any method of payment determined by the Secretary to be appropriate.".

(4) BATCH PROMPT PROCESSING OF CLAIMS.—Section 1842(c) of such Act (42 U.S.C. 1395u(c)) is amended—

(A) in paragraphs (2)(A) and (3)(A), by striking "Each" and inserting "Except as provided in paragraph (7), each"; and

(B) by adding at the end the following new paragraph:

"(7)(A) Each contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B), with respect to claims for payment for covered outpatient drugs shall provide for a payment cycle under which each carrier will, on a monthly basis, make a payment with respect to all claims which were received and approved for payment in the period since the most recent date on which such a payment was made with respect to the participating pharmacy or individual submitting the claim.

"(B) If payment is not issued, mailed, or otherwise transmitted within 5 days of when such a payment is required to be made under subparagraph (A), interest shall be paid at the rate used for purposes of section 3902(a) of title 31, United States Code (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after such 5-day period and ending on the date on which payment is made.".

(5) USE OF OTHER ENTITIES FOR COVERED OUTPATIENT DRUGS.—Section 1842(f) of such Act (42 U.S.C. 1395u(f)) is amended—

(A) by striking "and" at the end of paragraph (1),

(B) by striking the period at the end of paragraph (2) and inserting "; and", and

(C) by adding at the end the following:

"(3) with respect to activities related to covered outpatient drugs, any other private entity which the Secretary determines is qualified to conduct such activities.".

(6) DESIGNATED CARRIERS TO PROCESS CLAIMS OF RAILROAD RETIREES.—Section 1842(g) of such Act (42 U.S.C. 1395u(g)) is amended by inserting "(other than functions related to covered outpatient drugs)" after "functions".

(d) CONFORMING AMENDMENTS.—

(1)(A) Section 1833(a)(1) of such Act (42 U.S.C. 1395l(a)(1)) is amended—

(i) by striking "and" at the end of clause (R), and

(ii) by inserting before the semicolon at the end the following: ", and (T) with respect to

covered outpatient drugs, the amounts paid shall be as prescribed by section 1834(e)".

(B) Section 1833(a)(2) of such Act (42 U.S.C. 1395l(a)(2)) is amended in the matter preceding subparagraph (A) by inserting ", except for covered outpatient drugs," after "and (I) of such section".

(2) Section 1833(b)(2) of such Act (42 U.S.C. 1395l(b)(2)) is amended by inserting "or with respect to covered outpatient drugs" before the comma.

(3) The first sentence of section 1842(h)(2) of such Act (42 U.S.C. 1395u(h)(2)) is amended by inserting "(other than a carrier described in subsection (f)(3))" after "Each carrier".

(4) The first sentence of section 1866(a)(2)(A) of such Act (42 U.S.C. 1395cc(a)(2)(A)) is amended—

(A) in clause (i), by inserting "section 1834(e)," after "section 1833(b),", and

(B) in clause (ii), by inserting ", other than for covered outpatient drugs," after "provider)".

SEC. 4. MEDICARE REBATES FOR COVERED OUTPATIENT DRUGS.

(a) IN GENERAL.—Part B of title XVIII of the Social Security Act is amended by adding at the end the following new section:

"REBATES FOR COVERED OUTPATIENT DRUGS

"Sec. 1849. (a) REQUIREMENT FOR REBATE AGREEMENT.—

"(1) IN GENERAL.—In order for payment to be available under this part for covered outpatient drugs of a manufacturer dispensed or provided on or after January 1, 2002, subject to paragraph (2), the manufacturer must have entered into and have in effect a rebate agreement with the Secretary meeting the requirements of subsection (b) and an agreement to give equal access to discounts in accordance with subsection (e).

"(2) DEMONSTRATIONS.—The Secretary may conduct demonstrations with different forms of purchasing, such a competitive bidding, exclusive long-term contracts resulting in lower prices, and other devices to obtain the lowest possible price for quality pharmaceutical products. If the Secretary determines that a demonstration results in lower costs to the program and beneficiaries under this title than the rebate program under paragraph (1) while main-

taining quality and access to needed products, the Secretary may implement use of the demonstration regionally or nationally as an alternative to the rebate program. The Secretary shall from time to time report to Congress on such demonstrations.

"(b) TERMS, IMPLEMENTATION, AND ENFORCEMENT OF REBATE AGREEMENT.—

"(1) PERIODIC REBATES.—

"(A) IN GENERAL.—A rebate agreement under this section shall require the manufacturer to pay to the Secretary for each calendar quarter, not later than 30 days after the date of receipt of the information described in paragraph (2) for such quarter, a rebate in an amount determined under subsection (c) for all covered outpatient drugs of the manufacturer described in subparagraph (B).

"(B) DRUGS INCLUDED IN QUARTERLY REBATE CALCULATION.—Drugs subject to a rebate with respect to a calendar quarter are covered outpatient drugs which are single source and innovator multiple source drugs which are dispensed or provided during such quarter to individuals (other than individuals enrolled with a Medicare+Choice organization under part C)

eligible for benefits under this part, as reported to the Secretary.

"(2) INFORMATION FURNISHED TO MANUFACTURERS.—The Secretary shall report to each manufacturer, not later than 60 days after the end of each calendar quarter, information on the total number, for each covered outpatient drug described in paragraph (1)(B), of units of each dosage form, strength, and package size dispensed or provided under the plan during the quarter, on the basis of the data reported to the Secretary described in paragraph (1)(B).

"(3) PROVISION OF PRICE INFORMATION BY MANUFACTURER.—

"(A) QUARTERLY PRICING INFORMATION.—Each manufacturer with an agreement in effect under this section shall report to the Secretary, not later than 30 days after the last day of each calendar quarter, on the average manufacturer retail price and the average manufacturer non-retail price for each dosage form and strength of each covered outpatient drug described in paragraph (1)(B) for the quarter.

"(B) BASE QUARTER PRICES.—Each manufacturer of a covered outpatient drug with an

agreement under this section shall report to the Secretary, by not later than 30 days after the effective date of such agreement (or, if later, 30 days after the end of the base quarter), the average manufacturer retail price, for such base quarter, for each dosage form and strength of each such covered drug.

"(C) VERIFICATION OF AVERAGE MANUFACTURER PRICE.—The Secretary may inspect the records of manufacturers, and survey wholesalers, pharmacies, and institutional purchasers of drugs, as necessary to verify prices reported under subparagraph (A).

"(D) PENALTIES.—

"(i) CIVIL MONEY PENALTIES.—The Secretary may impose a civil money penalty on a manufacturer with an agreement under this section—

"(I) for failure to provide information required under subparagraph (A) on a timely basis, in an amount up to $10,000 per day of delay;

"(II) for refusal to provide information about charges or prices requested by the Secretary for purposes

of verification pursuant to subparagraph (C), in an amount up to $100,000; and

"(III) for provision, pursuant to subparagraph (A) or (B), of information that the manufacturer knows or should know is false, in an amount up to $100,000 per item of information.

Such civil money penalties are in addition to any other penalties prescribed by law. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

"(ii) TERMINATION OF AGREEMENT.—If a manufacturer with an agreement under this section has not provided information required under subparagraph (A) or (B) within 90 days of the deadline imposed, the Secretary may suspend the agreement with respect to covered out-

patient drugs dispensed after the end of such 90-day period and until the date such information is reported (but in no case shall a suspension be for less than 30 days).

"(4) LENGTH OF AGREEMENT.—

"(A) IN GENERAL.—A rebate agreement shall be effective for an initial period of not less than one year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

"(B) TERMINATION.—

"(i) BY THE SECRETARY.—The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall afford a manufacturer an opportunity for a hearing concerning such termination, but such hearing shall not delay the effective date of the termination.

"(ii) BY A MANUFACTURER.—A manufacturer may terminate a rebate agree-

ment under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

"(iii) EFFECTIVE DATE OF TERMINATION.—Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

"(iv) NOTICE TO PHARMACIES.—In the case of a termination under this subparagraph, the Secretary shall notify pharmacies and physician organizations not less than 30 days before the effective date of such termination.

"(c) AMOUNT OF REBATE.—

"(1) BASE REBATE.—Each manufacturer shall remit a basic rebate to the Secretary for each calendar quarter in an amount, with respect to each dosage form and strength of a covered outpatient drug equal to the product of—

"(A) the total number of units subject to rebate for such quarter, as described in subsection (b)(1)(B); and

"(B)(i) in the case of a single-source drug or an innovator-multiple source drug (other than insulin furnished over-the-counter), 15 percent of the average manufacturer retail price, or

"(ii) in the case of insulin furnished over-the-counter, 10 percent of the average manufacturer retail price.

"(2) ADDITIONAL REBATE.—Each manufacturer shall remit to the Secretary, for each calendar quarter, an additional rebate for each dosage form and strength of a single-source drug or an innovator-multiple source drug, in an amount equal to—

"(A) the total number of units subject to rebate for such quarter, as described in subsection (b)(1)(B), multiplied by

"(B) the amount, if any, by which the average manufacturer retail price for such drugs of the manufacturer exceeds the average manufacturer retail price for the base quarter, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. average) from the end of such base quarter to the month before the beginning of such calendar quarter.

"(3) DEPOSIT OF REBATES.—The Secretary shall deposit rebates under this section in the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

"(d) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by a manufacturer under this section is confidential and shall not be disclosed by the Secretary (or a carrier), except—

"(1) as the Secretary determines to be necessary to carry out this section,

"(2) to permit the Comptroller General to review the information provided, and

"(3) to permit the Director of the Congressional Budget Office to review the information provided.

"(e) AGREEMENT TO GIVE EQUAL ACCESS TO DISCOUNTS.—An agreement under this subsection by a manufacturer of covered outpatient drugs shall guarantee that the manufacturer will offer, to each wholesaler or retailer (or other purchaser representing a group of such wholesalers or retailers) that purchases such drugs on substantially the same terms (including such terms as prompt payment, cash payment, volume purchase, single-site delivery, the use of formularies by purchasers, and any other

terms effectively reducing the manufacturer's costs) as any other purchaser (including any institutional purchaser) the same price for such drugs as is offered to such other purchaser. In determining a manufacturer's compliance with the previous sentence, there shall not be taken into account prices that are merely nominal in amount or prices excluded under section 1927(c)(1)(C)(i).

"(f) DEFINITIONS.—For purposes of this section—

"(1) AVERAGE MANUFACTURER RETAIL PRICE.—The term 'average manufacturer retail price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the average price (inclusive of discounts for cash payment, prompt payment, volume purchases, and rebates (other than rebates under this section), but exclusive of nominal prices) paid to the manufacturer for the drug in the United States for drugs distributed to the retail pharmacy class of trade.

"(2) AVERAGE MANUFACTURER NON-RETAIL PRICE.—The term 'average manufacturer non-retail price' means, with respect to a covered outpatient drug of a manufacturer for a calendar quarter, the weighted average price (inclusive of discounts for cash payment, prompt payment, volume purchases, and rebates (other than rebates under this section),

but exclusive of nominal prices) paid to the manufacturer for the drug in the United States by hospitals and other institutional purchasers that purchase drugs for institutional use and not for resale.

"(3) BASE QUARTER.—The term 'base quarter' means, with respect to a covered outpatient drug of a manufacturer, the calendar quarter beginning April 1, 2002, or (if later) the first full calendar quarter during which the drug was marketed in the United States.

"(4) DRUG.—The terms 'innovator multiple source drug', 'noninnovator multiple source drug', and 'single source drug' have the meanings of those terms under section 1927(k)(7), except that the reference in such section to a 'covered outpatient drug' shall be considered a reference to a covered outpatient drug under this part.

"(5) MANUFACTURER.—The term 'manufacturer' means, with respect to a covered outpatient drug—

"(A) the entity whose National Drug Code number (as issued pursuant to section 510(e) of the Federal Food, Drug, and Cosmetic Act) appears on the labeling of the drug; or

"(B) if the number described in subparagraph (A) does not appear on the labeling of the drug, the person named as the applicant in a human drug application (in the case of a new drug) or the product license application (in the case of a biological product) for such drug approved by the Food and Drug Administration.".

(b) EXCLUSIONS FROM COVERAGE.—Section 1862(a) of such Act (42 U.S.C. 1395y(a)) is amended—

(1) by striking "and" at the end of paragraph (20),

(2) by striking the period at the end of paragraph (21) and inserting "; or", and

(3) by inserting after paragraph (21) the following new paragraph:

"(22) consisting of a covered outpatient drug (as described in section 1861(t)) furnished during a year for which the drug's manufacturer does not have in effect a rebate agreement with the Secretary that meets the requirements of section 1849 for the year.".

SEC. 5. EXPANSION OF MEDICARE PAYMENT ADVISORY COMMISSION.

(a) IN GENERAL.—Effective January 1, 2000, the membership of the Medicare Payment Advisory Commis-

sion (established under section 1805 of the Social Security Act, (42 U.S.C. 1395b–6)) shall be expanded to include 2 additional members, appointed by the Comptroller General of the United States, with expertise in the area of pharmacology and prescription drug benefit programs.

(b) APPLICATION OF PROVISIONS.—The provisions of paragraphs (2)(D), (3), and (4) of subsection (c) of such section (relating to ethical disclosure, terms, and compensation) shall apply to the additional members appointed under subsection (a) in the same manner as they apply to other members of the Commission.

SEC. 6. COVERAGE OF HOME INFUSION DRUG THERAPY SERVICES.

(a) IN GENERAL.—Section 1832(a)(2)(A) of the Social Security Act (42 U.S.C. 1395k(a)(2)(A)) is amended by inserting "and home infusion drug therapy services" before the semicolon.

(b) HOME INFUSION DRUG THERAPY SERVICES DEFINED.—Section 1861 of such Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

"Home Infusion Drug Therapy Services

"(uu)(1) The term 'home infusion drug therapy services' means the items and services described in paragraph

(2) furnished to an individual who is under the care of a physician—

"(A) in a setting described in section 1861(t)(5)(A)(ii),

"(B) by a qualified home infusion drug therapy provider (as defined in paragraph (3)) or by others under arrangements with them made by that provider, and

"(C) under a plan established and periodically reviewed by a physician.

"(2) The items and services described in this paragraph are such nursing, pharmacy, and related services (including medical supplies, intravenous fluids, delivery, and equipment) as are necessary to conduct safely and effectively a drug regimen through use of a covered home infusion drug (as defined in subsection (t)(5)), but do not include such covered home infusion drugs.

"(3) The term 'qualified home infusion drug therapy provider' means any entity that the Secretary determines meets the following requirements (or, in the case of a home health agency or an entity with respect to which the only items and services described in paragraph (2) furnished by the entity are enteral nutrition therapy services, meets any of the following requirements which the Secretary considers appropriate):

"(A) The entity is capable of providing or arranging for the items and services described in paragraph (2) and covered home infusion drugs.

"(B) The entity maintains clinical records on all patients.

"(C) The entity adheres to written protocols and policies with respect to the provision of items and services.

"(D) The entity makes services available (as needed) seven days a week on a 24-hour basis.

"(E) The entity coordinates all service with the patient's physician.

"(F) The entity conducts a quality assessment and assurance program, including drug regimen review and coordination of patient care.

"(G) The entity assures that only trained personnel provide covered home infusion drugs (and any other service for which training is required to provide the service safely).

"(H) The entity assumes responsibility for the quality of services provided by others under arrangements with the entity.

"(I) In the case of an entity in any State in which State or applicable local law provides for the licensing of entities of this nature, the entity (i) is

licensed pursuant to such law, or (ii) is approved, by the agency of such State or locality responsible for licensing entities of this nature, as meeting the standards established for such licensing.

"(J) The entity meets such other requirements as the Secretary may determine are necessary to assure the safe and effective provision of home infusion drug therapy services and the efficient administration of the home infusion drug therapy benefit.".

(c) PAYMENT.—

(1) IN GENERAL.—Section 1833 of such Act (42 U.S.C. 1395l) is amended—

(A) in subsection (a)(2)(B), by striking "or (E)" and inserting "(E), or (H)",

(B) in subsection (a)(2)(F), by striking "and" at the end,

(C) in subsection (a)(2)(G), by striking the semicolon and inserting "; and",

(D) by inserting after subsection (a)(2)(G) the following new subparagraph:

"(H) with respect to home infusion drug therapy services, the amounts described in section 1834(m);", and

(E) in the first sentence of subsection (b), by inserting "and home infusion drug therapy services" after "1861(kk)))".

(2) AMOUNT DESCRIBED.—Section 1834 of such Act is amended by adding at the end the following new subsection:

"(m) HOME INFUSION DRUG THERAPY SERVICES.—

"(1) IN GENERAL.—With respect to home infusion drug therapy services, payment under this part shall be made in an amount equal to the lesser of the actual charges for such services or the fee schedule established under paragraph (2).

"(2) ESTABLISHMENT OF FEE SCHEDULE.—

"(A) IN GENERAL.—The Secretary shall establish by regulation before the beginning of 2002 and each succeeding year a fee schedule for home infusion drug therapy services for which payment is made under this part. A fee schedule established under this subsection shall be on a per diem basis.

"(B) ADJUSTMENT FOR SERVICES FURNISHED BY INSTITUTIONS.—The fee schedule established by the Secretary under subparagraph (A) shall provide for adjustments in the case of home infusion drug therapy services for

which payment is made under this part that are furnished by a provider of services to avoid duplicative payments under this title for the service costs associated with such services.".

(d) CERTIFICATION.—Section 1835(a)(2) of such Act (42 U.S.C. 1395n(a)(2)) is amended—

(1) by striking "and" at the end of subparagraph (E),

(2) by striking the period at the end of subparagraph (F) and inserting "; and", and

(3) by inserting after subparagraph (F) the following:

"(G) in the case of home infusion drug therapy services, (i) such services are or were required because the individual needed such services for the administration of a covered home infusion drug, (ii) a plan for furnishing such services has been established and is reviewed periodically by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.".

(e) CERTIFICATION OF HOME INFUSION DRUG THERAPY PROVIDERS; INTERMEDIATE SANCTIONS FOR NONCOMPLIANCE.—

(1) TREATMENT AS PROVIDER OF SERVICES.—Section 1861(u) of such Act (42 U.S.C. 1395x(u)) is amended by inserting "home infusion drug therapy provider," after "hospice program,".

(2) CONSULTATION WITH STATE AGENCIES AND OTHER ORGANIZATIONS.—Section 1863 of such Act (42 U.S.C. 1395z) is amended by striking "and (dd)(2)" and inserting "(dd)(2), and (uu)(3)".

(3) USE OF STATE AGENCIES IN DETERMINING COMPLIANCE.—Section 1864(a) of such Act (42 U.S.C. 1395aa(a)) is amended—

(A) in the first sentence, by striking "an agency is a hospice program" and inserting "an agency or entity is a hospice program or a home infusion drug therapy provider,"; and

(B) in the second sentence—

(i) by striking "institution or agency" and inserting "institution, agency, or entity", and

(ii) by striking "or hospice program" and inserting "hospice program, or home infusion drug therapy provider".

(4) APPLICATION OF INTERMEDIATE SANCTIONS.—Section 1846 of such Act (42 U.S.C. 1395w–2) is amended—

(A) in the heading, by adding "AND FOR QUALIFIED HOME INFUSION DRUG THERAPY PROVIDERS" at the end,

(B) in subsection (a), by inserting "or that a qualified home infusion drug therapy provider that is certified for participation under this title no longer substantially meets the requirements of section 1861(uu)(3)" after "under this part", and

(C) in subsection (b)(2)(A)(iv), by inserting "or home infusion drug therapy services" after "clinical diagnostic laboratory tests".

(f) USE OF INTERMEDIARIES IN ADMINISTRATION OF BENEFIT.—Section 1816 of such Act (42 U.S.C. 1395h) is amended by adding at the end the following new subsection:

"(l) With respect to carrying out functions relating to payment for home infusion drug therapy services and covered home infusion drugs, the Secretary may enter into contracts with agencies or organizations under this section to perform such functions on a regional or national basis.".

(g) CONFORMING AMENDMENTS.—(1) Section 1834(h)(4)(B) of such Act (42 U.S.C. 1395m(h)(4)(B))

is amended by striking ", except that" and all that follows through "equipment".

(2) Section 1861(n) of such Act (42 U.S.C. 1395x(n)) is amended by adding at the end the following: "Such term does not include any home infusion drug therapy services described in section 1861(uu) or any covered outpatient drug used as a supply related to the furnishing of an item of durable medical equipment.".

(3) Section 1861(s)(8) of such Act (42 U.S.C. 1395x(s)(8)) is amended by inserting after "dental" the following: "devices or enteral and parenteral nutrients, supplies, and equipment".

SEC. 7. NO MARK-UP FOR DRUGS, BIOLOGICALS, OR PARENTERAL NUTRIENTS.

(a) IN GENERAL.—Section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o)) is amended to read as follows:

"(o)(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug, biological, or parenteral nutrient for which payment may be made under this part and the drug, biological, or parenteral nutrient is not paid on a cost or prospective payment basis as otherwise provided in this part, the payment amount established in this subsection

for the drug, biological, or parenteral nutrient shall be the lowest of the following:

"(A) The actual acquisition cost, as defined in paragraph (2), to the person submitting the claim for payment for the drug, biological, or parenteral nutrient.

"(B) 95 percent of the average wholesale price of such drug, biological, or parenteral nutrient, as determined by the Secretary.

"(C) For payments for drugs, biologicals, or parenteral nutrients furnished on or after January 1, 2000, the median actual acquisition cost of all claims for payment for such drugs, biologicals, or parenteral nutrients for the 12-month period beginning July 1, 1998 (and adjusted, as the Secretary determines appropriate, to reflect changes in the cost of such drugs, biologicals, or parenteral nutrients due to inflation, and such other factors as the Secretary determines appropriate).

"(D) The amount otherwise determined under this part.

"(2) For purposes of paragraph (1)(A), the term 'actual acquisition cost' means, with respect to such drugs, biologicals, or parenteral nutrients the cost of the drugs, biologicals, or parenteral nutrients based on the most eco-

nomical case size in inventory on the date of dispensing or, if less, the most economical case size purchased within six months of the date of dispensing whether or not that specific drug, biological, or nutrient was furnished to an individual whether or not enrolled under this part. Such term includes appropriate adjustments, as determined by the Secretary, for all discounts, rebates, or any other benefit in cash or in kind (including travel, equipment, or free products). The Secretary shall include an additional payment to cover costs reasonably incurred for administrative, storage, and handling. The Secretary shall consult with the provider community to simplify the accounting and reporting requirements used in calculating actual acquisition cost and may accept various averaging procedures, tax documents, and tax accounting procedures (such as last-in-first-out (LIFO) and first-in-first-out (FIFO)) instead of new reporting requirements.

"(3)(A) No payment shall be made under this part for drugs, biologicals, or parenteral nutrients to a person whose bill or request for payment for such drugs, biologicals, or parenteral nutrients does not include a statement of the person's actual acquisition cost.

"(B) A person may not bill an individual enrolled under this part—

"(i) any amount other than the payment amount specified in paragraph (1), (4), or (5) (plus any applicable deductible and coinsurance amounts), or

"(ii) any amount for such drugs, biologicals, or parenteral nutrients for which payment may not be made pursuant to subparagraph (A).

"(C) If a person knowingly and willfully in repeated cases bills one or more individuals in violation of subparagraph (B), the Secretary may apply sanctions against that person in accordance with subsection (j)(2).

"(4) The Secretary may pay a reasonable dispensing fee (less the applicable deductible and coinsurance amounts) for drugs or biologicals to a licensed pharmacy approved to dispense drugs or biologicals under this part, if payment for such drugs or biologicals is made to the pharmacy.

"(5) The Secretary shall pay a reasonable amount (less the applicable deductible and coinsurance amounts) for the services associated with the furnishing of parenteral nutrients for which payment is determined under this subsection.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) apply to drugs, biologicals, and parenteral nutrients furnished on or after January 1, 2001.

(c) ELIMINATION OF REPORT ON AVERAGE WHOLESALE PRICE.—Section 4556 of the Balanced Budget Act of 1997 is amended—

(1) by striking subsection (c); and

(2) by redesignating subsection (d) as subsection (c).

SEC. 8. TREATMENT OF PART B PREMIUM INCREASES RESULTING FROM ENACTMENT.

(a) ADDITIONAL PART B PREMIUM COVERED UNDER QMB AND SLMB PROGRAMS.—Any increase in the premium under part B of title XVIII of the Social Security Act resulting from the amendments made by this Act is covered for qualified Medicare beneficiaries and for special low income Medicare beneficiaries under the medicaid program under clauses (i) and (iii) of section 1902(a)(10)(A) of such Act.

(b) SEPARATE LISTING OF PORTION OF PREMIUM COVERING PRESCRIPTION DRUG BENEFIT.—The Secretary of Health and Human Services shall provide, in any statement of premiums established under section 1839 of the Social Security Act, for a separate statement of the portion of such premiums which is attributable to the amendments made by this Act.

(c) WAIVER OF ADDITIONAL PORTION FOR MEDICARE BENEFICIARIES HAVING ACTUARIALLY EQUIVA-

LENT COVERAGE.—The Secretary of Health and Human Services shall establish a method under which the portion of the premium described in subsection (b) is waived (and not collected) for any individual enrolled under part B of title XVIII of the Social Security Act who demonstrates that the individual has coverage (through a group health plan, Medicare supplemental policy, under the medicaid program under title XIX of the Social Security Act, through the Department of Veterans Affairs, or otherwise) that is actuarially equivalent to the coverage provided under such part.

SEC. 9. EFFECTIVE DATE.

Except as otherwise provided, the amendments made by this Act apply to items and services furnished on or after January 1, 2002.

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